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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,454	10/27/2000	Miri Seiberg	JBPO518	5753
7590 Philip S. Johnson, Esq. Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003			EXAMINER CHONG, YONG SOO	
			ART UNIT 1627	PAPER NUMBER
			MAIL DATE 03/14/2011	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

09/698,454

Applicant(s)

SEIBERG ET AL.

Examiner

YONG CHONG

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/C200)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 1/10/11.

Claim(s) 1-29 have been cancelled. Claim(s) 30-34 are pending and examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified or repeated below for Applicant's convenience.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 34 is rejected under 35 U.S.C. 102(a) as being anticipated by Kelly et al. (WO 99/36050, of record).

Kelly et al. teach using soy extract for protecting skin from UV damage (abstract). The soy extract of Kelly et al. is obtained by the extraction with a mixture of organic solvents and water (pg. 11, lines 23-27). The recitation of "non-denatured" soy product is inherent in the reference because soy beans are extracted without using enzymes and/or temperature. The compositions of Kelly et al. may also contain preservatives (pg. 10, lines 8-9). Examiner notes that Kelly et al. teach that the ratio of organic solvent in water may be as low as 0.1%. It is highly unlikely that 0.1% of ethanol in

water will cause protein denaturing. Moreover, the soy extract containing compositions herein possess the same skin protecting or trypsin inhibitory activity as claimed because a composition and its properties are inherent. Applicant has not differentiated between soy beans that have or do not have this property by their structure or process steps.

Response to Arguments

Applicant argues that Kelly et al. completely fails to teach with any specificity a non-denatured soy product containing trypsin inhibitory activity. Applicant argues against using a 0.1% solvent solution to extract soy. The Seiberg Declaration filed on 12/4/09 states that a ratio of organic solvent in water as low as 0.1% would not effectively facilitate the intent and purpose of Kelly's compositions. Indeed, a much higher organic solvent content is necessary to extract isoflavones from soy.

This is not persuasive because it is Examiner's position that the pharmaceutical composition taught by Kelly et al. comprising soy extract is not denatured nor is it devoid of STI activity. The Kelly reference does not claim to have denatured soy bean extract. No where in the extraction methods do both references state the use of enzymes, elevated temperature, or acids, which are well-known methods of denaturing proteins. The denaturing of Kelly's soy beans so as not to contain soy trypsin inhibitor proteins are merely a conjecture on the part of the Applicants, which are not supported by factual evidence.

The Kelly et al. reference states that soy may be extracted with a mixture of organic solvents such as ethanol, chloroform, acetone, ethyl acetate, and water, with

the ratio of organic solvent to water may be 0.1 to 99.9%, preferably 40-60% (col. 11, lines 23-27). Furthermore, Applicant's specification states that soybeans can be extracted with an ethanol/water mixture in a way that the STI activity is still retained (pg. 8, lines 1-5). Since Kelly et al. teaches an extraction using an ethanol/water mixture, how is it that the soy product is denatured in the Kelly et al. process and not denatured in Applicant's claimed process when the extraction methods are essentially the same? Applicant is requested to show factual evidence and not circumstantial evidence that the cited prior art methods results in a denatured soy product devoid of STI activity. With regard to the Seiberg Declaration filed on 12/4/09, Applicant is reminded that the ratio of organic solvent to water in Kelly et al. is not limited to 0.1% but covers a much broader range. It is this range taught by Kelly et al. that encompasses the example of ethanol/water found in Applicant's specification.

Applicant argues that the Hu Declaration demonstrates the difference between the soy products of the claimed invention (non-denatured soy) and the soy products disclosed by Kelly. It is demonstrated that Kelly's soy products do not exhibit trypsin inhibition activity.

The Hu Declaration under 37 CFR 1.132 filed 1/10/11 is insufficient to overcome the rejection of claim 34 based upon Kelly et al. (WO 99/36050, of record) as set forth in the last Office action.

First of all, it is confusing why the Hu Declaration states that the soy products of Kelly (Sample B) do not exhibit trypsin inhibition activity when clearly there is trypsin inhibition of 1.44%. Secondly, Kelly does not heat at any point in the extraction

process, whereas Sample B was heated on a hot plate for 1 hour as described in the Hu Declaration. It is confusing why Hu would heat the extract, even though it is known that elevated temperatures contribute to denaturing. In this manner, nothing can be said about the soy products of Kelly from the data in the Hu Declaration.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 30-33 are rejected under 35 U.S.C. 103(a) as being obvious over Tokuyama (JP 5-320061, translation of record) in view of Mizue (JP 62-36304, of record).

The instant claims are directed to a method of evening skin tone and texture, treating acne, increasing elasticity and firmness, reducing the shine and oiliness, treating cellulite of a mammal by administering a composition comprising non-denatured soy product and a stabilizing system.

Tokuyama teach using aqueous or organic extract of soy beans and/or other legumes in unaltered form in topical dermatological compositions for treating a variety of skin diseases and conditions such as scratches, cuts, burns, rashes, eruptions, pimples, blackheads, chapping skin, eczema, dermatitis, etc. (abstract, sections 0009, 0010, 0033, 0035, and Table 4). Moreover, the soy bean extracts applied to the skin as cosmetic products showed "a smoothing effect on the texture of the skin," "a wrinkle stretching rejuvenating effect," "skin softening and moisturizing effect," and "an aging preventing effect" (sections 0045-0047).

Examiner notes that the term "beautifying effect" is often used in Japanese publications as synonymous to "skin whitening effect." With respect to the limitations "non-denatured" and "having trypsin inhibitory activity," the Tokuyama reference teaches the same extraction method as disclosed in the instant application (Examples 2-3). Therefore, the soy product of Tokuyama is inherently non-denatured and possesses trypsin inhibitory activity.

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical

chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Furthermore, Examiner notes that the limitations regarding process at which the soy product is made is given little patentable weight since the claims are drawn to a method of using the composition comprising the soy product.

It is respectfully pointed out that even though product-by-process claims are limited by and defined by the process; determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorp*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). "The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

However, Tokuyama fail to explicitly disclose the stabilizing system of the instant claims.

Mizue teach stabilizing soy extracts in cosmetic compositions with preservatives such as parabens and chelating agents such as disodium EDTA (pg. 6 of translation and Examples).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to modify the cosmetic or dermatological soy extract containing compositions of Tokuyama by adding a stabilizing agent, such as a preservative.

A person of ordinary skill in the art would have been motivated to do this to prevent spoilage of the soy extract as suggested by Mizue.

Response to Arguments

Applicant argues that the legumes extracts of Tokuyama are denatured and therefore do not possess trypsin inhibitory activity. Two groups of legume extracts are taught: (A) organic extractions using 90% alcohol and (B) aqueous extracts of legumes which are boiled. As shown in the Hu Declaration, since extracts from 60% ethanol did not have trypsin inhibition activity, it would be expected that 90% would not either. Furthermore, boiling contributes to denaturing, therefore group B would not be expected to have non-denatured soy.

This is not persuasive because it is confusing why Applicant would continue to compare heated extracts of soy and pass them off as the same ones taught by the prior

art, in this case, Tokuyama. Applicant is reminded that in Examples 2 and 3, the soy extracts were not heated. Furthermore, the soy used by Tokuyama were black soybeans, which are different than the ones used in the Hu Declaration.

Applicant argues that genistin and daidzin, two major soy isoflavones, were shown to not have trypsin inhibition activity.

This is not persuasive because Applicant is apparently confused with the earlier assertion regarding tyrosinase inhibitory activity. For the record, the Examiner is not making the connection between isoflavones and trypsin inhibition activity, therefore the arguments directed to genistin and daidzin are irrelevant. Furthermore, Tokuyama does not recite that its soy beans are denatured. Tokuyama does not disclose extraction techniques involving high temperatures or acids that cause denaturing; therefore all of the inherent properties of soy beans, including STI's protease inhibitory activity, are present. The reason for the tyrosinase inhibitory activity argument is because of the following. The specification clearly defines "denaturation" as a loss of enzyme activity (pg. 7, first paragraph). If this were the case with Tokuyama, the soy beans would not possess any enzyme activity. This is not the case, as Tokuyama clearly recites that "black soybeans" possess "tyrosinase inhibitory activity" in Table 1. Therefore, the soy beans recited in Tokuyama are not denatured and inherently possess STI's protease inhibitory activity.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S. Chong/
Primary Examiner, Art Unit 1627

YSC